[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32 and 35

[NRC-2014-0030]

RIN 3150-AI63

Medical Use of Byproduct Material - Medical Event Definitions and Training and Experience

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft guidance document entitled "Draft Guidance for the Proposed Rule 'Medical Use of Byproduct Material – Medical Events Definitions, Training and Experience, and Clarifying Amendments.'" This draft guidance document addresses implementation of the NRC's proposed rule amending its medical use of byproduct material regulations.

DATES: Submit comments by **[INSERT DATE 120 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID NRC-2014-0030. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: 3WFN-06-A44MP, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on accessing information and submitting comments, see "Accessing Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Donna-Beth Howe, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-7848; e-mail: Donna-Beth.Howe@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments.

A. Accessing Information

Please refer to Docket ID NRC-2014-0030 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document by any of the following methods:

- **Federal Rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID NRC-2014-0030.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**

You may access publicly available documents online in the NRC Library at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The draft guidance document is available in ADAMS under Accession No. ML13172A189.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2014-0030 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in you comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information

before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Discussion.

In the Proposed Rule section of this issue of the *Federal* Register, the NRC published the proposed rule, "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments" (RIN 3150-AI63, NRC-2014-0030). The proposed rule would amend requirements in parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations*, for reporting and notification of a medical event for permanent implant brachytherapy; training and experience for authorized users, medical physicists, Radiation Safety Officers and nuclear pharmacists; and measuring molybdenum contamination and reporting of failed technetium and rubidium generators. The rule also proposes changes that would allow Associate Radiation Safety Officers to be named on a medical use license and other clarifying revisions to the regulations. Finally, the proposed rule addresses a request filed in a petition for rulemaking (PRM), PRM-35-20, to "grandfather" certain board-certified individuals so that they are exempt from certain training and experience requirements.

In conjunction with the proposed rule, the NRC has developed a draft guidance document which would provide guidance to a licensee or applicant for implementation of the proposed regulations. The draft guidance document is intended for use by applicants, licensees, Agreement States, and the NRC staff. The draft guidance document (ADAMS Accession No. ML13172A189) has three parts: the first two are revisions to existing guidance in the NUREG-1556, "Consolidated Guidance About Materials Licenses", series of volumes for medical uses and commercial nuclear pharmacies; and the third part is a series of questions and answers to assist licensees in understanding and implementing the new proposed regulatory changes. The NUREG-1556 documents mainly provide guidance to applicants in the

completion and submission of materials license applications. The documents also include model procedures that an applicant may want to use when developing its radiation safety program, as well as tools that licensees may employ when completing the corresponding material license applications.

Parts 1 and 2 of the draft guidance document will be incorporated into the next comprehensive revision of relevant volumes of NUREG-1556.

Part 3 of the draft guidance document will be added to the NRC's Medical Uses Licensee Toolkit Web site (http://www.nrc.gov/materials/miau/med-use-toolkit.html) when the questions and answers are finalized.

Dated at Rockville, Maryland, this 10th day of March, 2014.

Laura A. Dudes, Director,
Division of Materials Safety and State Agreements,
Office of Federal and State Materials,
and Environmental Management Programs.

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